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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,990	11/21/2003	Horst Heirler	028622-0125	8166
22428	7590	02/13/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			ROYDS, LESLIE A	
		ART UNIT	PAPER NUMBER	
		1614		

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,990	HEIRLER, HORST	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 December 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) 11 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>27 October 2005</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-19 are presented for examination.

Applicant's Amendment and Information Disclosure Statement (IDS) filed October 27, 2005 have each been received and entered into the application. The amendment was found to be non-compliant and notice to that effect was sent November 23, 2005. Applicant's subsequent Amendment filed December 6, 2005 in response to the notice was received and entered into the application. Accordingly, the specification at paragraphs [0012] and [0018] has been amended and claims 2, 4, 7, 10-11 and 14 have also been amended. As reflected by the attached, completed copy of form PTO/SB/08 (one page total), the Examiner has considered the cited references.

In view of the amendments and remarks made herein, the objections to claims 2, 7, 10-11 and 13-14 as set forth at (i) of page 2; the objections to claims 14-16 and 18 as set forth at (ii) of page 2; the objections to claims 4 and 7 for minor informalities as set forth at page 3; the rejection of claims 11-13 under 35 U.S.C. 112, second paragraph, as set forth at (II) of pages 4-5; and the rejection of claims 1-19 under 35 U.S.C. 112, second paragraph, as set forth at (III) of pages 5-6 of the previous Office Action dated April 27, 2005 have each been hereby withdrawn.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicant's amendment to claim 14, removing the word "about" at line 2 of the claim has been noted. However, insofar as Applicant failed to remove the word "about" at line 3 of the

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claim, the present rejection of claim 14, and also those claims that depend from such a claim (i.e., claims 15-19), made under 35 U.S.C. 112, second paragraph, remains proper and is repeated below.

Claims 14-19 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention, for the reasons already made of record at pages 3-4 of the previous Office Action dated April 27, 2005.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al. (WO 97/38593; 1997), already of record, for the reasons of record set forth at pages 6-7 of the previous Office Action dated April 27, 2005.

Applicant relies upon the decision in *Rapport v. Dement* (254 F.3d 1053, Fed.Cir. 2001) in support of their position that the Examiner has not provided sufficient basis for determining anticipation of the present claim. Applicant states that the Examiner alleges that the claimed method to regulate and normalize fat metabolism for diabetics was anticipated because Bell teaches the use of a bar was used to treat nighttime hypoglycemia in a diabetic patient.

Applicant asserts that the difference between the present claims and Bell et al. is that the problem underlying the present invention is the regulation and normalization of lipid metabolism in diabetic patients, not the treatment of nighttime hypoglycemia in a diabetic patient. Applicant submits that the lipid component of the bar disclosed by Bell et al. is of minor importance and is only described in two lines of the disclosure as comprising medium chain and long chain triglycerides. Applicant further states that Bell et al. is completely silent on the issue of lipid metabolism and there is no evidence that the amount to delay gastric emptying as disclosed by Bell et al. correlates with the amount necessary to regulate and normalize lipid metabolism. Applicant further submits that there is no basis in MPEP §2113 to shift the burden to Applicant to supply evidence that the Patent Office must supply to demonstrate a lack of correlation between the amounts required by the present claims and the amounts taught by the reference.

Applicant's amendments and remarks have each been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

First, it is noted that each application before the Office is decided on its own merits. While the Examiner has considered the decision in *Rapport v. Dement*, the present fact pattern is distinctly different from that contained in *Rapport*. Therefore, Applicant's reliance on such a decision to establish error in the propriety of the present rejection is not deemed persuasive because the present set of facts compel a conclusion of anticipation for the reasons given below and those already made of record.

Aside from the fact that the subject matter and facts before the Office are distinctly different than that of *Rapport*, the most fundamental distinction between the *Rapport* case and the rejection of the presently claimed subject matter lies in the fact that the rejection in *Rapport*

was made under the doctrine of inherency. No such inherency rejection has been set forth on the record in the present case. Thus, the considerations for rejections made under inherency as instructed by *Rapport* are not considered relevant in the present case.

Applicant asserts that the difference between the present claims and Bell et al. lies in that the problem underlying the present invention is the regulation and normalization of lipid metabolism in diabetic patients, not the treatment of nighttime hypoglycemia in a diabetic patient, and, therefore, concludes that the Examiner's allegation that Bell et al. anticipates the presently claimed subject matter is in error.

However, Applicant is reminded that the present claims are not drawn to the objective of regulating and normalizing fat metabolism in a diabetic patient. The present claims are drawn to a method for supplementing the diet of a subject with diabetes mellitus as recited in independent claim 1. Applicant's attention is directed thereto. Thus, Applicant's argument that Bell et al. fails to show this feature of Applicant's invention is not found persuasive because the features upon which Applicant relies (i.e., the regulation and normalization of lipid metabolism) is not the objective recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It has already been established on the record that the subject of Bell et al. (i.e., a diabetic patient) is identical to that of the present claims (i.e., a subject with diabetes mellitus) and the composition of Bell et al. contains a lipid source comprising medium chain and long chain triglycerides (page 2, lines 31-34 and page 4, lines 13-14), which meets Applicant's limitation of "comprising administering to the subject medium-chain triglycerides or a composition

comprising medium-chain triglycerides” as recited in present claim 1. While it is acknowledged that the method of Bell et al. is drawn to the treatment of nighttime hypoglycemia in a diabetic patient, the very fact that the diabetic subject(s) intended to receive such a composition would necessarily have consumed a diet of food renders the concomitant administration of such a composition to necessarily meet the requirement for “supplementing the diet of a subject with diabetes mellitus” as recited in present claim 1. Thus, the objective of supplementing the diet of a diabetic patient is the necessary result of administering the composition disclosed by Bell et al. to such a patient.

Applicant’s assertion that the lipid component of the bar disclosed by Bell et al. is of minor importance because lipids are only described in two lines of the disclosure as comprising medium-chain and long-chain triglycerides is absolutely not found to be persuasive. The “importance” of a component contained within a composition is most certainly not directly proportional to the amount of discussion devoted to such a component in the corresponding disclosure. Such an assertion is merely the interpretation of counsel and is not supported by any evidence. In fact, the very teaching that the lipid source may be anywhere from 2% to 40% by weight of the composition clearly indicates the Bell et al. contemplated embodiments of the invention wherein almost half of the composition was lipid. In other words, embodiments of the invention were contemplated where lipid was a major component of the composition.

Applicant alleges that Bell et al. is silent on the issue of lipid metabolism and there is no evidence that the amount of Bell et al. (i.e., the amount to delay gastric emptying) correlates with the amount necessary to regulate and normalize lipid metabolism. However, while it may be true that Bell et al. is silent on the issue of lipid metabolism, it is once again noted that the objective

of the present claims is diet supplementation, not modulation of lipid metabolism. Therefore, the fact that Bell et al. is silent on the issue of lipid metabolism is not relevant.

It appears that Applicant intends to show a difference in the amount of the composition of Bell et al. administered to the diabetic patient and the amount of the presently claimed composition. However, it is noted that Applicant only claims an amount sufficient to regulate and normalize fat metabolism, but fails to provide any quantification of such an amount either in the claims or in the specification. Thus, Applicant relies solely on the statement of the function to define the amount. Absent any factual evidence or direction to the contrary, there is no reason to doubt that the teaching of 2%-40% lipid by weight of the composition disclosed by Bell et al. would not be capable of regulating and normalizing fat metabolism. Insofar as Applicant has failed to provide any evidence or sound scientific reasoning as to why the amounts of Bell et al. would not ultimately achieve such an objective, the rejection remains proper for the reasons already made of record.

Applicant's allegation that there is no basis in MPEP §2113 to shift the burden to Applicant to supply evidence that the Patent Office must supply to show that the amounts required by the reference are not the same as those required by the present claims is not persuasive. There is no need to supply any evidence beyond what has already been stated in the reference to show that the amounts taught by Bell et al. would not achieved the same objective as that of the present claims. Because Applicant has failed to patentably distinguish the amounts by defining the functional language in some sort of quantity, there is no reason to believe that the amount of Bell et al. was not sufficient to achieve this objective. In the absence of such evidence

in the specification or claims, it is Applicant's responsibility to show how or why the effect on lipid metabolism would not be expected to occur at the amount disclosed by Bell et al.

For these reasons and those already made of record at pages 6-7 of the previous Office Action dated April 27, 2005, rejection of claim 1 under 35 U.S.C. 102(b) remains proper and is maintained.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. (WO 97/38593; 1997) in view of The Merck Index (Monographs 5382, 5383, 6788, 9918 and 9932), Zawistowski et al. (WO 01/91587; 2001), Laughlin et al. (U.S. Patent No. 5,470,839; 1995), Stedman's Medical Dictionary (22nd Edition, 1973; page 1400), Mendy (U.S. Patent No. 4,407,821; 1983) and DeMichele et al. (U.S. Patent No. 5,780,451; 1998), each already of record, for the reasons of record set forth at pages 8-15 of the previous Office Action dated April 27, 2005.

Applicant states that Bell et al. does not relate to the control of lipid metabolism and further submits that the combination of teachings between Bell and the other cited references enumerated at pages 14-15 of Applicant's remarks do not substantiate an obviousness rejection.

Applicant's amendments and remarks have each been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Applicant is reminded that the claims are drawn to the objective of supplementing the diet of a diabetic subject (which is met by the teaching of Bell et al.), not the control of lipid metabolism. Applicant's attention is directed above to the response provided under "Claim Rejection-35 U.S.C. 102" for a discussion as to why the teachings of Bell et al. are relevant to the presently claimed subject matter.

Applicant's allegation that the combined teachings of the cited references do not substantiate an obviousness rejection has been considered, but fails to be persuasive. Applicant has set forth arguments and discussion related to individual references and discrete combinations of the references without clearly addressing the combined teachings of all of the references as a whole as they were set forth in the rejection at pages 8-15 of the previous Office Action. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited reference. See *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, it is also noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

For these reasons and those already made of record at pages 8-15 of the previous Office Action dated April 27, 2005, the rejection remains proper and is maintained.

Conclusion

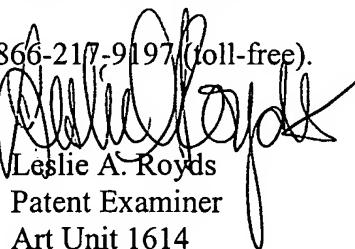
Rejection of claims 1-19 remains proper and is maintained.

No claims of the present application are allowed.

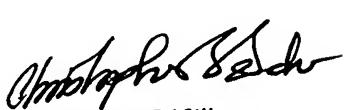
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Leslie A. Royds
Patent Examiner
Art Unit 1614

February 6, 2006


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600